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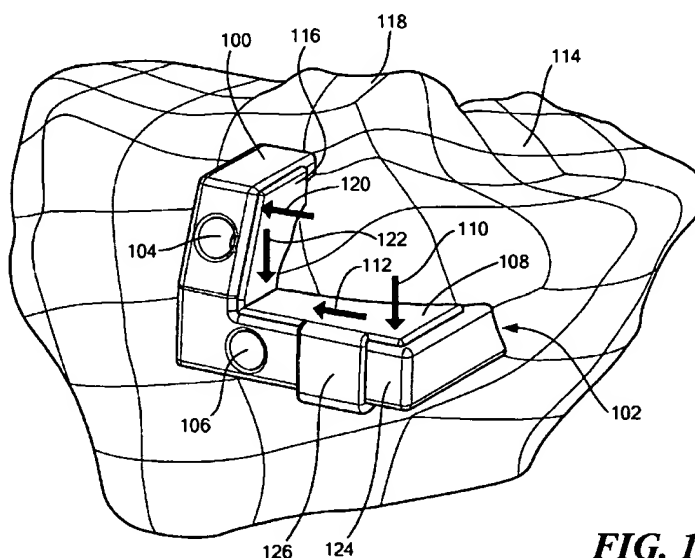


FIG. 1

(57) Abstract: The present invention is directed to a surgical cutting guide for guiding a surgical instrument along a cutting path located on a biological tissue. The surgical guide includes a contact surface that conforms to a surface associated with the tissue and at least one guide for restricting movement of a surgical instrument in a first direction and for allowing the movement of the surgical instrument in a second direction along a cutting path across the surface of the tissue. The guide further contains a stop for restricting movement of the surgical instrument in the second direction along the cutting path. The stop is based at least, in part, on patient specific information.

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Surgical Cutting Guide

Cross Reference to Related Applications

[0001] The present application claims the benefit of U.S. Application Serial No. 60/943,726,
5 entitled "SURGICAL CUTTING GUIDE" filed June 13, 2007, which application is incorporated
herein by reference in its entirety.

Technical Field

[0002] The present invention relates to surgical tools, and more particularly, to surgical tools
such as surgical cutting guides.

10

Background Art

[0003] When performing cuts with blades, saws, or other surgical instruments during
surgical interventions, surgeons typically have good control of the surgical instrument with
regard to direction and depth of tissue penetration. However, sometimes a surgical
instrument may slip, be deflected, or stray from its intended cutting path. When a surgical
15 instrument strays from its indented cutting path, it may inadvertently injure or cut other
tissues.

[0004] For example, in knee arthroplasty, a surgeon may intend to preserve one or more
tibial spines. When performing a horizontal tibial cut, the surgeon typically guides the blade
20 in an anteroposterior direction. The surgeon guides the blade path so as to stay clear of the
tibial spines. However, if the surgeon accidentally misdirects the instrument or if the
instrument is deflected from its intended path, the blade path may extend into the tibial
spines or other local tissues. This unintended cut of the tibial spines may result in the loss of
ligament stability.

25

[0005] Deviation of the surgical instrument from its intended cutting path may also have
harmful effects when performing surgical interventions in other parts of the body. For

example, in the spine, deviation of a surgical instrument may result in neural damage or damage to bony or disc structures. In the hip, deviation of an instrument from the cutting path may potentially result in neurovascular damage or damage to bony and ligamentous structures. In a shoulder, deviation of the instrument path may potentially result in
5 neurovascular or muscular damage.

[0006] Deviation from the cutting path may also lead to other unintended consequences. For example, failure to follow a cutting path may later result in misalignment or poor positioning of an implant. A poor fit for an implant may result in complete failure of the implant or
10 other complications.

Summary of the Invention

[0007] Embodiments of the present invention are directed to preventing unintended and inadvertent cuts to tissues during surgical interventions. In one embodiment of the invention, a surgical cutting guide is used to prevent unintended and inadvertent cuts. The surgical
15 cutting guide includes a contact surface that conforms to a surface associated with a biological tissue and at least one guide for restricting movement of a surgical instrument in a first direction and for allowing the movement of the surgical instrument in a second direction along a cutting path across the surface of the tissue. The guide further includes a stop for restricting movement of the surgical instrument in the second direction along the cutting
20 path. The stop is based at least, in part, on patient specific information.

[0008] In some embodiments, the guide may be configured to abut the tissue and the abutment of the guide and tissue defines at least part of the cutting path of the surgical instrument. The stop may also be configured to abut the tissue.
25

[0009] Each of the stop, the guide, and the contact surface may have several configurations. For example, the stop may be configured to contact a cutting surface of the surgical instrument. The surgical instrument may be a blade or a saw. The stop may also be perpendicular to a cut plane defined by the guide. The guide may be one of a slot, an
30 aperture, and a cutting plane. The placement, location, orientation, and shape of the stop

may be based at least, in part, on patient specific information. The contact surface may be a mirror image of an uncut surface of the tissue. Also, the contact surface may have a plurality of concavities and/or a plurality of convexities. The contact surface may also be based at least, in part, on patient specific information. The contact surface may be made to conform to a variety of tissues, for example, the tissue may be one of a joint, an articular surface, a spine, a structure adjacent to one of a joint, an articular surface, and a spine.

[0010] In some exemplary embodiments of the invention, the patient specific information may be based on an image of the tissue. The images may be one of a CT image, a spiral CT image, an MRI image, an ultrasound image, a digital tomosynthesis image, and an optical coherence tomograph. In other embodiments, the patient specific information is based at least, in part, on intra-operative measurement of the tissue.

[0011] In some embodiments of the present invention, the stop may protect the tibial spines. In a more particular embodiment, the guide guides movement of the surgical instrument towards the tibial spines and the stop prevents the surgical instrument from cutting the tibial spines. In other embodiments, the stop protects one of a ligament, a vessel, a nerve, a muscle, a bony structure, and a cartilaginous structure. Further embodiments of the present invention may be put to use in one of a knee, a hip, an ankle, a foot, a shoulder, an elbow, a wrist, a hand, a spine, a vertebral endplate, a skull, a pedicle, a posterior element, and a spinous process.

[0012] In another embodiment of the present invention, the surgical cutting guide includes a surface that is a mirror image of a joint, a spine, or a structure adjacent to a joint or spine. The surgical cutting guide further includes a guide or a guide aperture that directs movement of a surgical instrument along a predetermined path. A stop prevents the surgical instrument from deviating from the predetermined path. The location of said stop may be based, at least in part, on patient specific information.

[0013] In further related embodiments of the invention, the stop may protect one or more tibial spines. The guide or guide aperture may direct movement of the surgical instrument

towards the tibial spine, wherein the stop keeps the surgical instrument clear of the tibial spine. The guide or guide aperture may direct movement of a saw and/or blade. The surgical cutting guide may be used in a knee, a hip, an ankle, a foot, a shoulder, an elbow, a wrist, a hand, a spine, a vertebral endplate, a skull, a pedicle, a posterior element, or a spinous process. The surface may have a plurality of concavities and/or a plurality of convexities. The stop may be perpendicular to a cut plane defined by the at least one of a guide and a guide aperture.

[0014] In accordance with another embodiment of the invention, a surgical tool for a knee joint includes a portion that is a mirror image of a joint, a spine, and/or a structure adjacent to a joint or a spine. The surgical tool further includes a guide or a guide aperture that directs movement of a surgical instrument along a predetermined path. A stop inhibits the surgical instrument from deviating from the predetermined path, wherein said stop protects a tibial spine.

[0015] In accordance with related embodiments of the invention, the surgical tool may be used for a total knee arthroplasty or a partial knee arthroplasty. The position of the stop may be based, at least in part, on patient specific information. The guide or guide aperture may direct movement of the surgical instrument towards the tibial spine, wherein the stop keeps the surgical instrument clear of the tibial spine. The guide or guide aperture may direct movement of a saw and/or blade. The surface may have a plurality of concavities and/or a plurality of convexities. The stop may be perpendicular to a cut plane defined by the at least one of a guide and a guide aperture.

[0016] In accordance with another embodiment of the invention, a cutting guide includes a portion that is a mirror image of a joint, a spine, and/or a structure adjacent to a joint or a spine. The cutting guide further includes a guide or a guide aperture for directing movement of a surgical instrument along a predetermined path. A stop prevents a surgical instrument from deviating from the predetermined path, where the stop may protect a ligament, a vessel, a nerve, a muscle, a bony structure, and/or a cartilaginous structure.

[0017] In accordance with related embodiments of the invention, the surgical tool may be used in a total knee arthroplasty or a partial knee arthroplasty. The position of the stop may be based, at least in part, on patient specific information. The guide and/or guide aperture may direct movement of the surgical instrument towards the ligament, vessel, nerve, muscle, bony structure, and/or cartilaginous structure, but the stop may keep the surgical instrument clear of the ligament, vessel, nerve, muscle, bony structure, and/or cartilaginous structure. The guide or guide aperture may direct movement of one of a saw and a blade. The portion may be a surface having a plurality of concavities and a plurality of convexities. The stop may be perpendicular to a cut plane defined by the at least one of a guide and a guide aperture.

[0018] In accordance with another embodiment of the invention, a cutting guide includes a portion that is a mirror image of a joint, a spine, and/or a structure adjacent to the joint or spine. The cutting guide further includes a guide or a guide aperture that directs movement of a surgical instrument along a predetermined path. A stop inhibits the surgical instrument from deviating from the predetermined path. The stop is integrated into said cutting guide.

[0019] In accordance with related embodiments of the invention, the position of the stop is based, at least in part, on patient specific information. The stop may protect the tibial spines. The guide or guide aperture may direct movement of the surgical instrument towards the tibial spines, wherein the stop keeps the surgical instrument clear of the tibial spines. The guide or guide aperture may direct movement of a saw and/or blade. The surgical cutting guide may be used in a knee, a hip, an ankle, a foot, a shoulder, an elbow, a wrist, a hand, a spine, a vertebral endplate, a skull, a pedicle, a posterior element, or a spinous process. The surface may have a plurality of concavities and/or a plurality of convexities. The stop may be perpendicular to a cut plane defined by the at least one of a guide and a guide aperture.

[0020] In accordance with another embodiment of the invention, a cutting guide includes a portion that is a mirror image of a joint, a spine, and/or a structure adjacent to the joint or spine. The cutting guide further includes a guide or a guide aperture that directs movement

of a surgical instrument along a predetermined path. A stop inhibits the surgical instrument from deviating from the predetermined path. The stop is attached to said cutting guide.

[0021] In accordance with related embodiments of the invention, the position of the stop is based, at least in part, on patient specific information. The stop may protect the tibial spine. The guide or guide aperture may direct movement of the surgical instrument towards the tibial spine, wherein the stop keeps the surgical instrument clear of the tibial spine. The guide or guide aperture may direct movement of a saw and/or blade. The surgical cutting guide may be used in a knee, a hip, an ankle, a foot, a shoulder, an elbow, a wrist, a hand, a spine, a vertebral endplate, a skull, a pedicle, a posterior element, or a spinous process. The surface may have a plurality of concavities and/or a plurality of convexities. The attachment may be via a block or a linkage. The stop may be perpendicular to a cut plane defined by the at least one of a guide and a guide aperture.

[0022] In accordance with another embodiment of the invention, a cutting guide includes a portion that is a mirror image of a joint, a spine, and/or a structure adjacent to the joint or spine. The cutting guide further includes a guide or a guide aperture that directs movement of a surgical instrument along a predetermined path. A stop inhibits the surgical instrument from deviating from the predetermined path. The position, orientation or shape of the stop is derived using patient specific anatomic information.

[0023] In accordance with related embodiments of the invention, the position, orientation, or shape of said stop may allow for intra-operative adjustments. The stop may protect the tibial spine. The guide or guide aperture may direct movement of the surgical instrument towards the tibial spine, wherein the stop keeps the surgical instrument clear of the tibial spine. The guide or guide aperture may direct movement of a saw and/or blade. The cutting guide may be used in a knee, a hip, an ankle, a foot, a shoulder, an elbow, a wrist, a hand, a spine, a vertebral endplate, a skull, a pedicle, a posterior element, or a spinous process. The surface may have a plurality of concavities and/or a plurality of convexities. The stop may be perpendicular to a cut plane defined by the at least one of a guide and a guide aperture.

[0024] In accordance with another embodiment of the invention, a surgical cutting guide includes a surface that is a mirror image of at least one of a joint, a spine, and a structure adjacent to one of a joint and a spine. The surgical cutting guide further includes at least one of a guide and a guide aperture for directing movement of a surgical instrument along a predetermined path. The position or shape or orientation of the at least one of a guide and a guide aperture is based on patient specific information and provides for at least one of a predetermined cut angulation and a predetermined cut height.

[0025] In accordance with related embodiments of the invention, the surgical tool may further include a stop for inhibiting the surgical instrument from deviating from the predetermined path. The position of the stop may be based, at least in part, on patient specific information. The stop may protect the tibial spine. At least one of a guide and a guide aperture may direct movement of the surgical instrument towards the tibial spine, but the stop may keep the surgical instrument clear of the tibial spine. The at least one of a guide and a guide aperture may be used to direct movement of a saw or a blade with regard to, for example, a knee, a hip, an ankle, a foot, a shoulder, an elbow, a wrist, a hand, a spine, a vertebral endplate, a skull, a pedicle, a posterior element, or a spinous process.

[0026] In accordance with related embodiments of the above-described embodiments of the invention, the patient specific information may be based, at least in part, on an intra-operative measurement of the joint, the spine, or the structure adjacent to the joint and the spine. Alternatively, or in combination with the intra-operative measurement, the patient specific information may be based on an image of the joint, the spine, or the structure adjacent to the joint and the spine. The image may be a CT image, a spiral CT image, an MRI image, an ultrasound image, a digital tomosynthesis image, and an optical coherence tomograph.

[0027] In accordance with another embodiment of the invention, a surgical tool includes a template having at least one a guide for directing movement of a surgical instrument along a predetermined path. At least one insert is attached to the guide or guide aperture. The at least one insert protects the template from the surgical instrument.

[0028] In accordance with related embodiments of the invention, the template may be made of plastic, and the insert is made of metal. The template may be a mold or a rapid prototype. The insert may be removably attached to the template. The insert may snap onto the
5 template.

[0029] Embodiments of the present invention are also directed to a method for guiding a surgical instrument. The method includes providing a surgical cutting guide having a contact surface that conforms to a surface associated with a biological tissue and at least one guide
10 for restricting movement of a surgical instrument in a first direction and for allowing the movement of the surgical instrument in a second direction along the cutting path across the surface of the tissue. Providing the surgical guide further includes ascertaining patient specific information associated with the tissue and incorporating a stop into the guide for restricting movement of the surgical instrument in the second direction along the cutting
15 path. The stop is based at least, in part, on patient specific information.

[0030] The method may further include securing the cutting guide to the tissue and cutting the tissue by using the cutting guide to guide the surgical instrument along the cutting path. The cutting guide may be secured to the guide by using anchor screws. In one embodiment
20 of the method, the tissue may be cut so that a cutting surface of the surgical instrument contacts the stop. A blade and/or a saw may be used to cut the tissue.

[0031] The method may include several configurations of the surgical cutting guide. For example, the guide and/or the stop may be configured to abut the surface of the tissue. The
25 guide may also be configured into a slot, an aperture, and/or a cutting plane. The placement, location, orientation, and shape of the stop may be based at least, in part, on patient specific information. For example, in one embodiment the stop may be configured to be perpendicular to a cut plane defined by the guide.

[0032] The contact surface may be configured so that at least a portion of the contact surface
30 is a mirror image of an uncut surface of the tissue. The contact surface may also be based at

least, in part, on patient specific information. The contact surface may further include a plurality of concavities and a plurality of convexities.

[0033] In some embodiments of the method, the patient specific information may be
5 ascertained through imaging the tissue. Imaging may be accomplished by CT imaging, CT
spiral imaging, MRI imaging, ultrasound imaging, digital tomosynthesis, and/or optical
coherence tomography. In other embodiments of the method, patient specific information
may be ascertained through intra-operative measuring.

10 [0034] Embodiments of the method may be applied to a variety of tissues, for example, the
tissue may be one of a joint, an articular surface, a spine, and a structure adjacent to one of a
joint, an articular surface, and a spine. Embodiments of the method may also be put to use in
one of a knee, a hip, an ankle, a foot, a shoulder, an elbow, a wrist, a hand, a spine, a
vertebral endplate, a skull, a pedicle, a posterior element, and a spinous process.

15 [0035] In another embodiment of the surgical cutting guide, the cutting guide includes a
contact surface that conforms to a surface associated with the tissue and at least one guide for
restricting movement of a surgical instrument in a first direction and for allowing the
movement of the surgical instrument in a fifth direction along a cutting path into the tissue.
20 The cutting guide further includes a stop for restricting movement of the surgical instrument
in a second direction. The stop is based at least, in part, on patient specific information. In
some embodiments, this guide may be configured to abut the tissue and the abutment of the
guide and tissue defines at least part of the cutting path of the surgical instrument. The stop
may also be configured to abut the tissue.

25 [0036] Each of the stop, the guide, and the contact surface may have several configurations.
For example, the stop may be configured to contact a cutting surface of the surgical
instrument. The surgical instrument may be a blade or a saw. The stop may also be
perpendicular to a cut plane defined by the guide. The guide may be one of a slot, an
30 aperture, and a cutting plane. The placement, location, orientation, and shape of the stop
may be based at least, in part, on patient specific information. The contact surface may be a

mirror image of an uncut surface of the tissue. Also, the contact surface may have a plurality of concavities and/or a plurality of convexities. The contact surface may also be based at least, in part, on patient specific information. The contact surface may be made to conform to a variety of tissues, for example, the tissue may be one of a joint, an articular surface, a spine, a structure adjacent to one of a joint, an articular surface, and a spine.

[0037] In some exemplary embodiments of the invention, the patient specific information may be based on an image of the tissue. The images may be one of a CT image, a spiral CT image, an MRI image, an ultrasound image, a digital tomosynthesis image, and an optical coherence tomograph. In other embodiments, the patient specific information is based at least, in part, on intra-operative measurement of the tissue.

[0038] In some embodiments of the present invention, the stop may protect the tibial spines. In a more particular embodiment, the guide guides movement of the surgical instrument towards the tibial spines and the stop prevents the surgical instrument from cutting the tibial spines. In other embodiments, the stop protects one of a ligament, a vessel, a nerve, a muscle, a bony structure, and a cartilaginous structure. Further embodiments of the present invention may be put to use in one of a knee, a hip, an ankle, a foot, a shoulder, an elbow, a wrist, a hand, a spine, a vertebral endplate, a skull, a pedicle, a posterior element, and a spinous process.

[0039] In another embodiment of the method for guiding a surgical instrument, the method includes providing a surgical cutting guide having a contact surface that conforms to a surface associated with a tissue and at least one guide for restricting movement of a surgical instrument in a first direction and for allowing the movement of the surgical instrument in a fifth direction along the cutting path into the tissue. Providing the surgical guide further includes ascertaining patient specific information associated with the tissue and incorporating a stop into the guide for restricting movement of the surgical instrument in the second direction. The stop is based at least, in part, on patient specific information. The method may further include securing the cutting guide to the tissue and cutting the tissue by using the cutting guide to guide the surgical instrument along the cutting path. The cutting

guide may be secured to the guide by using anchor screws. In one embodiment of the method, the tissue may be cut so that a cutting surface of the surgical instrument contacts the stop. A blade and/or a saw may be used to cut the tissue.

5 [0040] The method may include several configurations of the surgical cutting guide. For example, the guide and/or the stop may be configured to abut the surface of the tissue. The guide may also be configured into a slot, an aperture, and/or a cutting plane. The placement, location, orientation, and shape of the stop may be based at least, in part, on patient specific information. For example, in one embodiment the stop may be configured to be
10 perpendicular to a cut plane defined by the guide.

[0041] The contact surface may be configured so that at least a portion of the contact surface is a mirror image of an uncut surface of the tissue. The contact surface may also be based at least, in part, on patient specific information. The contact surface may further include a
15 plurality of concavities and a plurality of convexities.

[0042] In some embodiments of the method, the patient specific information may be ascertained through imaging the tissue. Imaging may be accomplished by CT imaging, CT spiral imaging, MRI imaging, ultrasound imaging, digital tomosynthesis, and/or optical
20 coherence tomography. In other embodiments of the method, patient specific information may be ascertained through intra-operative measuring.

[0043] Embodiments of the method may be applied to a variety of tissues, for example, the tissue may be one of a joint, an articular surface, a spine, and a structure adjacent to one of a
25 joint, an articular surface, and a spine. Embodiments of the method may also be put to use in one of a knee, a hip, an ankle, a foot, a shoulder, an elbow, a wrist, a hand, a spine, a vertebral endplate, a skull, a pedicle, a posterior element, and a spinous process.

30

Brief Description of the Drawings

[0044] The foregoing features of the invention will be more readily understood by reference to the following detailed description, taken with reference to the accompanying drawings, in which:

5

[0045] Fig. 1 is an isometric view of a patient specific surgical tool, in accordance with one embodiment of the invention;

[0046] Fig. 2 depicts exemplary medial and lateral cuts made to the tibial plateau while
10 preserving the tibial spines, in accordance with one embodiment of the invention;

[0047] Fig. 3 depicts exemplary angular cuts on the tibial plateau;

[0048] Fig. 4 depicts a tibial plateau with an exemplary cut plane that fails to preserve at
15 least a portion of the tibial spines;

[0049] Fig. 5 depicts an example of a method for guiding a surgical instrument, in accordance with one embodiment of invention; and

20 [0050] Fig. 6 depicts further examples of a method for guiding a surgical instrument, in accordance with one embodiment of the invention.

Detailed Description of Specific Embodiments

[0051] Illustrative embodiments of the present invention are directed to a patient specific surgical cutting guide. Fig. 1 is an isometric view of a patient specific surgical cutting guide
25 100, in accordance with one embodiment of the invention. More particularly, the exemplary surgical cutting guide 100 shown in Fig. 1 is a patient specific cutting guide (also referred to in the art as a jig or template) that may be used, for example, in performing a knee arthroplasty. In other embodiments, the surgical guide 100 may be used in performing operations elsewhere in the body, such as a joint, a hip, an ankle, a foot, a shoulder, an

elbow, a wrist, a hand, a spine, a vertebral endplate, a skull, a pedicle, a posterior element, and/or a spinous process.

[0052] The surgical cutting guide 100 includes a contact surface 102 that conforms to at least
5 a portion of a surface of a biological tissue to be treated or the structures adjacent to the
tissue, as described in U.S. Application Serial No. 11/671,745, incorporated herein by
reference in its entirety. In preferred embodiments, the contact surface 102 conforms to a
substantially uncut portion of a surface of a biological tissue to be treated or the structures
adjacent to the tissue. When in use, the contact surface 102 of the cutting guide 100 is
10 placed in contact with the tissue and/or structures adjacent to the tissue. The conforming
structure of the contact surface 102 helps ensure proper positioning and orientation of the
cutting guide 100. The contact surface 102 may be used to contact a variety of different
tissues. For example, the tissue may be, without limitation, at least one of an articular
surface, cartilage, subchondral bone and/or other tissue surface and shape. In some
15 embodiments the contact surface 102 may be a "mirror image" or "negative" of the surface
of the tissue. Yet, in other embodiments, the contact surface 102 may only have portions that
conform to the surface of the tissue. The contact surface 102 may be, without limitation, a
surface with one or more concavities and/or one or more convexities. For example, the
contact surface 102 may have, without limitation, a single convexity; a plurality of
20 convexities; a single concavity; a plurality of concavities; or at least one convexity and at
least one concavity.

[0053] In order to fix the contact surface 102 to the tissue, the surgical cutting guide 100
may contain drill bushing holes 104 and 106. These drill bushing holes 104, 106 allow the
25 cutting guide 100 to be anchored to the tissue and/or adjacent structures by using anchoring
screws or drill pins inserted through the drill bushing holes 104, 106. In various
embodiments, the drill bushing holes 104, 106 include metal inserts (or other hard material)
to prevent degradation of the cutting guide when drilling. Other attachment mechanisms
known in the art may be used to fix the contact surface 102 to the tissue.

30

[0054] Patient specific information may advantageously be used to ensure that the contact

surface 102 properly conforms to the surface of the tissue. Patient specific information includes, but is not limited to one or more intra-operative measurements and/or one or more electronic images. Images and measurements of the surface of the tissue provide object coordinates that define the surface and shape of the tissue. The electronic images of the tissue may be from, without limitation, a CT image, a spiral CT image, an MRI image, an ultrasound scan, digital tomosynthesis, or optical coherence tomography. The object coordinates may be utilized to shape a portion of the cutting guide 100. For example, once the patient specific information is ascertained, rapid prototyping or other manufacturing techniques may be used to adapt the contact surface 102 to the patient's particular tissue structure. In various embodiments, a mold may be made to form the contact surface 102 to the particular tissue structure of the patient. Alternatively, the patient specific information may be used to select a pre-made guide or template that has a good fit with a patient's particular tissue structure.

[0055] The surgical cutting guide 100 includes at least one guide 108 for restricting movement of the surgical instrument in a first direction 110 and allowing movement of the surgical instrument in a second direction 112 along a cutting path across the surface of the tissue. The guide 108 defines at least a portion of the cutting path of the surgical instrument along the surface of the tissue. The cutting path may be predetermined based upon the patient specific information and the type of surgical intervention being performed. In one embodiment, as depicted in Fig. 1, the guide 108 is a simple cutting plane. But the guide 108 may also be formed from one or more cutting planes, apertures, slots, and/or holes to accommodate surgical instruments such as drills, reamers, curettes, k-wires, screws and saws. Moreover, a single cutting guide 100 may include a plurality of guides 108. The guide 108 or plurality of guides 108 may be positioned and/or adjusted based on the patient specific information to form a predetermined instrument cutting path for a desired surgical intervention.

[0056] During a knee arthroplasty, the guides 108 may direct horizontal medial 206 and lateral 204 cuts of the tibia plateau 114, as depicted (before and after) in Fig. 1 and Fig. 2. Yet, in another embodiment, the guides 108 may provide for angular cuts rather than

horizontal or near horizontal cuts. Fig. 3 shows exemplary angular cuts 302 on the tibial plateau 304. The angulation of the cut may be, without limitation, anterior to posterior and/or lateral to medial. The position or placement of the horizontal or angular guide 108 on the surgical cutting guide 100 relative to the contact surface 102 may be patient specific, and, for example, may control, among other dimensions, the cut height on the tibial plateau.

[0057] As depicted in Fig. 1, the guide 108 may be configured to abut the surface of the tissue. In other words, at least a portion of an edge of the guide 108 may be in contact with the surface of the tissue. The abutment of the guide against the surface of the tissue may define a portion of the cutting path across the surface of the tissue. Yet, in other embodiments, the guide 108 may not be configured to contact the surface of the tissue and is, instead, set back from the surface of the tissue.

[0058] The cutting guide 100 also includes a stop 116 for restricting movement of the surgical instrument in the second direction along the cutting path. The stop 116 is used to prevent a surgical instrument from deviating from its intended path and ensures that the instrument will stay clear of tissue structures to be preserved. A single cutting guide may contain a plurality of stops 116. The stop 116 may be used to protect a variety of structures such as ligaments, vessels, nerves, muscles, bony structures, and cartilaginous structures. For example, in a knee arthroplasty, the patient specific surgical cutting guide 100 may include a guide 108 for directing a horizontal or near horizontal cut of the tibial plateau 114. In accordance with one aspect of the invention, Fig. 2 depicts exemplary medial 204 and lateral 206 cuts made to the tibial plateau 114 with properly preserved tibial spines 202. Whereas Fig. 4 depicts a tibial plateau showing a cut plane 402 that fails to preserve a portion of the tibial spines 404. In order to preserve the one or more tibial spines, the cutting guide 100 may include a medial stop 116 and/or a lateral stop 116. The stops 116 may be substantially perpendicular to the intended cutting plane defined by the guide 108 such as the stop 116 depicted in Fig. 1. In other embodiments, the stop 116 may be at other angles relative to the intended cutting plane, such as at 60, 70, or 80 degrees. Like the guide 108, the stop 116 may be configured to abut the surface of the tissue, or the stop 116 may be configured to be set back from the surface of the tissue. In various embodiments of the

invention, the stop 116 may have a straight, curved, and/or complex surface. The stop 116 may have one or more convexities and/or concavities. Any shape known in the art is possible for the stop 116.

5 [0059] The placement, location, orientation, and shape of the stop 116 may be determined based on the surface of the tissue, the tissue structures to be preserved, and the type of surgical intervention to be performed. For example, during a knee arthroplasty, the guide 108 may direct the movement of the surgical instrument in a horizontal cut of the tibial plateau 114. However, an over extension of the horizontal cut of the tibial plateau may result
10 in undercutting the tibial spines and the attached anterior and/or posterior cruciate ligaments of the knee. To solve this problem, the stop 116, as depicted in Fig. 1, is designed so that a horizontal cut into the tibial plateau 114 will stay clear of the tibial spines 118. The stop 116 prevents the cutting surface of the surgical instrument, such as a saw or blade, from extending too far into the tibial plateau 114 and undercutting the tibial spines 118. The stop
15 116 prevents over extension of the surgical instrument by coming into mechanical contact with the surgical instrument and thus prevents any further progression of the surgical instrument into the tibial spines 118. The guide 108 and the stop 116 work together to guide the movement of the surgical instrument towards the tibial spines 118, while at the same time keeping the surgical instrument clear of the tibial spines 118.

20 [0060] In another embodiment, as depicted in Fig. 1, the stop 116 may effectively be used as a guide by restricting the movement of the surgical tool in a third direction 120 and allowing the movement of the surgical instrument in a fourth direction 122 along the cutting path across the surface of the tissue. The guide 108 may effectively be used as a stop by
25 restricting the movement of the surgical instrument in the fourth direction 122 along the cutting path.

[0061] In another embodiment of the present invention, an oscillating saw may be used to cut the tissue. In such an embodiment, the guide 108 of the surgical cutting guide 100 may
30 restrict movement of the saw in a first direction 110 and may allow movement of the saw in

a fifth direction into the tissue. A stop 116 may restrict movement of the saw in a second direction 112.

[0062] The placement, location, orientation, and shape of both the guide 108 and the stop 116 may be determined based on patient specific information. For example, patient specific information in the form of imaging data, which may be, without limitation, a CT image, a spiral CT image, an MRI image, an ultrasound scan, digital tomosynthesis, or optical coherence tomograph may be utilized to identify tissue structures that need to be preserved. The identification of tissue structures may be performed automatically or with the help of an operator. The guide 108 and the stop 116 may then be designed to ensure that the surgical instrument and its cutting path will stay clear of the tissue structure to be preserved. Intra-operative measurement of the tissue structure is another form of patient specific information that may be used to define the placement, location, orientation, and shape of the guide 108 and/or the stop 116.

[0063] Once the placement, location, orientation, and shape of the guide 108 and the stop 116 is determined, there are several ways to incorporate them into the cutting guide 100. In one embodiment the contact surface 102, the guide 108 and the stop 116 may be made of the same material. In such an embodiment, the contact surface 102, the guide 108, and the stop 116 may be molded or rapid prototyped as a single unitary structure. In another embodiment, the guide 108 and stop 116 may be integrated into the cutting guide 100. For example, the guide 108 and stop 116 may be machined into the cutting guide 100. However, in a preferred embodiment, the guide 108 and the stop 116 are made from hard materials, such as metal, in order to prevent the surgical instrument from penetrating and degrading the cutting guide 100. In such an embodiment, the guide 108 and stop 116 may be attached to the cutting guide 100 in an appropriate location and orientation. Fig. 1 depicts such an embodiment. The cutting guide 100 includes a template 124 that includes contact surface 102. The template 124 may be made from a material such as a plastic. The template 124 may be made from a mold or through rapid prototyping based on patient specific information. An insert 126 may be secured onto the template 124. As depicted in Fig. 1, the insert forms both the guide 108 and the stop 116. But in other embodiments separate inserts

126 may form each of the stop 116 and the guide 108. The insert 126 may be made from a hard material, such as metal, in order to protect the template 124 from the cutting surface of the surgical tool. The insert 126 may be removably attached to the template through the use of clips, pins, and/or anchor screws. In another embodiment, the guide 108 and stop 116
5 may be attached to the cutting guide 100 via a block or a linkage as described in U.S. Application serial No. 11/671,745, incorporated herein by reference in its entirety.

[0064] In another embodiment, the guide 108 and/or stop 116 are incorporated into the cutting guide in such way that intra-operative adjustments may be made to the position, orientation and/or shape of the guide 108 or stop 116. A pivot, space, ratchet or jack like
10 mechanism may be used, without limitation, to adjust the guide 108 or stop 116. For example, the stop 116 may be capable of sliding along the cutting guide 100 and, then, locking into place at the appropriate position. Such intra-operative adjustments may be performed, without limitation, to ensure optimal ligament balancing.

15 [0065] Fig. 5 depicts an example of a method for guiding the surgical instrument. The method may include imaging the tissue structure to be treated 502. Imaging of the tissue may be accomplished as described above through CT imaging, spiral CT imaging, MRI imaging, ultrasound scanning, digital tomosynthesis, or optical coherence tomography. Once
20 the tissue is imaged, patient specific information is ascertained based upon the image 504. In another embodiment the patient specific information may be ascertained from intra-operative measurements of the tissue. Once the patient specific information is ascertained, the stop 116 may be incorporated into the surgical cutting guide 100 based at least, in part, on the patient specific information 506. The placement, location, orientation, and shape of the stop
25 116 on the cutting guide 100 may be determined based upon the surface of the tissue, the tissue structures to be preserved, the type of surgical intervention to be performed, and/or the cutting path of the surgical instrument. As depicted in Fig. 6, the placement, location, orientation, and shape of the guide 108 may also be determined based upon similar considerations and patient specific information 602. The structure of the conforming contact
30 surface 102 may also be determined based at least, in part, on the ascertained patient specific information 604. The stop 116, the guide 108, and the contact surface 102 may be

incorporated onto the cutting guide 100 as attachments to the cutting guide 100, as integral to the cutting guide 100, and/or as a single unitary structure. As discussed above, the stop 116, the guide 108, and the contact surface 102 may be molded or rapid prototyped as a single unitary structure. In another embodiment, the stop 116 may be attached onto a pre-made cutting guide 100 or template 124 that has a good fit with a patient's particular tissue structure. In yet another embodiment, the stop 116, guide 108, or contact surface 102 may be integrated into the guide through a machining process.

[0066] Once the surgical cutting guide is provided, the surgical guide 100 may be secured to the tissue 606. The conforming contact surface 102 of the surgical cutting guide 100 is placed on the mating surface of the tissue and/or adjacent tissue structures. The surgical cutting guide 100 may be secured to the tissue using the bushing holes 104, 106 and anchor screws. The surgical cutting guide 100 may also be secured to the tissue using surgical glue, bone cement, or any other appropriate fastening means. Once the surgical cutting guide 100 is secured to the tissue, the tissue may be cut with the surgical instrument using the cutting guide 100 to guide the surgical instrument along the cutting path 608. The at least one guide 108 restricts the movement of the surgical instrument in the first direction 110, but allows the movement of the surgical instrument in the second direction 112 along the cutting path across the surface of the tissue. The stop 116 restricts the movement of the surgical instrument in the second direction 112 along the cutting path. The stop 116 restricts movement of the surgical instrument in the second direction 112 by coming in contact with the surgical instrument, and more particularly, the cutting surface of the surgical instrument. After the cut is complete, the cutting guide 100 may be removed or left inside the body post-operatively depending on the particular type of surgical intervention.

[0067] The described embodiments of the invention are intended to be merely exemplary and numerous variations and modifications will be apparent to those skilled in the art. All such variations and modifications are intended to be within the scope of the present invention as defined in the appended claims.

What is claimed is:

1. A surgical cutting guide for guiding a surgical instrument along a cutting path located on a biological tissue, the cutting guide comprising:
 - 5 a contact surface that conforms to a surface associated with the tissue;
at least one guide for restricting movement of a surgical instrument in a first direction and for allowing the movement of the surgical instrument in a second direction along a cutting path across the surface of the tissue; and
a stop for restricting movement of the surgical instrument in the second direction
 - 10 along the cutting path, wherein the stop is based at least, in part, on patient specific information.
2. A surgical cutting guide according to claim 1, wherein the guide is configured to abut the tissue and the abutment of the guide and tissue defines at least part of the cutting path of the
- 15 surgical instrument.
3. A surgical cutting guide according to claim 1, wherein the stop is configured to abut the tissue.
- 20 4. A surgical cutting guide according to claim 1, wherein the stop is configured to contact a cutting surface of the surgical instrument.
5. A surgical guide according to claim 1, wherein at least a portion of the contact surface is a mirror image of an uncut surface of the tissue.
- 25 6. A surgical cutting guide according to claim 1, wherein the biological tissue is one of a joint, an articular surface, a spine, a structure adjacent to one of a joint, an articular surface, and a spine.
- 30 7. A surgical cutting guide according to claim 1, wherein the contact surface is based at least, in part, on patient specific information.

8. A surgical cutting guide according to claim 1, wherein the patient specific information is based at least, in part, on intra-operative measurement of the tissue.
- 5 9. A surgical cutting guide according to claim 1, wherein the patient specific information is based on an image of the tissue.
10. A surgical cutting guide according to claim 9, wherein the image is one of a CT image, a spiral CT image, an MRI image, an ultrasound image, a digital tomosynthesis image, and an
10 optical coherence tomograph.
11. A surgical cutting guide according to claim 1, wherein the guide is one of a slot, an aperture, and a cutting plane.
- 15 12. A surgical cutting guide according to claim 1, wherein one of a placement, location, orientation, and shape of the stop is based at least, in part, on patient specific information.
13. A surgical cutting guide according to claim 1, wherein the stop protects at least one of a ligament, a vessel, a nerve, a muscle, a bony structure, and a cartilaginous structure.
20
14. A surgical cutting guide according to claim 1, wherein the stop protects tibial spines.
15. A surgical cutting guide according to claim 14, wherein the at least one guide guides movement of the surgical instrument towards the tibial spines and wherein the stop prevents
25 the surgical instrument from cutting the tibial spines.
16. A surgical cutting guide according to claim 1, wherein the surgical instrument is one of a blade or a saw.

17. A surgical cutting guide according to claim 1 for use in one of a knee, a hip, an ankle, a foot, a shoulder, an elbow, a wrist, a hand, a spine, a vertebral endplate, a skull, a pedicle, a posterior element, and a spinous process.

5 18. A surgical cutting guide according to claim 1, wherein the contact surface has a plurality of concavities and a plurality of convexities.

19. A surgical cutting guide according to claim 1, wherein the stop is perpendicular to a cut plane defined by the at least one guide.

10

20. A method for guiding a surgical instrument, the method comprising:

providing a surgical cutting guide having a contact surface that conforms to a surface associated with a tissue and at least one guide for restricting movement of a surgical instrument in a first direction and for allowing the movement of the surgical instrument in a second direction along the cutting path across the surface of the tissue, wherein providing the surgical guide includes:

15

ascertaining patient specific information associated with the tissue; and

incorporating a stop into the guide for restricting movement of the surgical instrument in the second direction along the cutting path, wherein the stop is based at least, in part, on patient specific information.

20

21. A method according to claim 20, further comprising securing the cutting guide to the tissue.

25 22. A method according to claim 22, further comprising cutting the tissue by using the cutting guide to guide the surgical instrument along the cutting path.

23. A method according to claim 20, further comprising configuring the at least one guide to abut the surface of the tissue.

30

24. A method according to claim 20, further comprising configuring the stop to abut the surface of the tissue.

25. A method according to claim 22, further comprising cutting the tissue so that a cutting
5 surface of the surgical instrument contacts the stop.

26. A method according to claim 20, further comprising configuring the contact surface so that at least a portion of the contact surface is a mirror image of an uncut surface of the tissue.
10

27. A method according to claim 20, wherein the tissue is one of a joint, an articular surface, a spine, and a structure adjacent to one of a joint, an articular surface, and a spine.

28. A method according to claim 20, further comprising configuring the contact surface,
15 based at least, in part, on patient specific information.

29. A method according to claim 20, further comprising configuring one of a placement, location, orientation, and shape of the stop based at least, in part, on patient specific information.
20

30. A method according to claim 20, further comprising intra-operative measuring of the tissue in order to ascertain patient specific information.

31. A method according to claim 20, further comprising imaging the tissue in order to
25 ascertain patient specific information.

32. A method according to claim 31, wherein the imaging is one of CT imaging, CT spiral imaging, MRI imaging, ultrasound imaging, digital tomosynthesis, and optical coherence tomography.
30

33. A method according to claim 20, further comprising configuring the guide into one of a slot, an aperture, and a cutting plane.

34. A method according to claim 22, further comprising using one of a blade and a saw to cut the tissue.

35. A method according to claim 20 for use in one of a knee, a hip, an ankle, a foot, a shoulder, an elbow, a wrist, a hand, a spine, a vertebral endplate, a skull, a pedicle, a posterior element, and a spinous process.

36. A method according to claim 20, further comprising configuring the contact surface with a plurality of concavities and a plurality of convexities.

37. A method according to claim 20, further comprising configuring the stop to be perpendicular to a cut plane defined by the at least one guide.

38. A method according to claim 20, the cutting guide is secured to the tissue using anchoring screws.

39. A surgical cutting guide comprising:

a surface that is a mirror image of at least one of a joint, an articular surface, a spine, and a structure adjacent to one of a joint, an articular surface, and a spine;

at least one of a guide and a guide aperture for directing movement of a surgical instrument along a predetermined path; and

a stop that prevents the surgical instrument from deviating from the predetermined path, wherein location of the stop is based at least, in part, on patient specific information.

40. A surgical tool comprising:

a portion that is a mirror image of at least one of a joint, an articular surface, a spine, and a structure adjacent to one of a joint, an articular surface, and a spine;

at least one of a guide and a guide aperture for directing movement of a surgical instrument along a predetermined path; and

a stop for inhibiting the surgical instrument from deviating from the predetermined path.

41. A surgical tool for a knee joint, the surgical tool comprising:

5 a portion that is a mirror image of one of a joint, an articular surface, a spine, and a structure adjacent to a joint, an articular surface, or a spine;

at least one of a guide and a guide aperture for directing movement of a surgical instrument along a predetermined path; and

10 a stop that prevents the surgical instrument from deviating from the predetermined path, wherein the stop protects a tibial spine.

42. The surgical tool of claim 41, wherein the surgical tool is used for a total knee arthroplasty.

15 43. The surgical tool of claim 41, wherein the surgical tool is used for a partial knee arthroplasty.

44. The surgical tool according to claim 41, wherein the position of the stop is based at least, in part, on patient specific information.

20

45. A cutting guide comprising:

a portion that is a mirror image of one of a joint, an articular surface, a spine, and a structure adjacent to a joint, an articular surface, or a spine;

25 at least one of a guide and a guide aperture for directing movement of a surgical instrument along a predetermined path; and

a stop that prevents a surgical instrument from deviating from the predetermined path, wherein the stop protects at least one of a ligament, a vessel, a nerve, a muscle, a bony structure, and a cartilaginous structure.

30 46. The cutting guide of claim 45, wherein the surgical tool is used for a total knee arthroplasty.

47. The cutting guide of claim 45, wherein the surgical tool is used for a partial knee arthroplasty.

5 48. A cutting guide comprising:

a portion that is a mirror image of at least one of a joint, an articular surface, a spine, and a structure adjacent to one of a joint, an articular surface, and a spine;

at least one of a guide and a guide aperture for directing movement of a surgical instrument along a predetermined path; and

10 a stop for preventing the surgical instrument from deviating from the predetermined path, wherein the stop is integrated into the cutting guide.

49. A cutting guide comprising:

a portion that is a mirror image of at least one of a joint, an articular surface, a spine, and a structure adjacent to one of a joint, an articular surface, and a spine;

15 at least one of a guide and a guide aperture for directing movement of a surgical instrument along a predetermined path; and

a stop for preventing the surgical instrument from deviating from the predetermined path, wherein the stop is attached to the cutting guide.

20

50. The cutting guide according to claim 49, wherein the attachment is via a block.

51. The cutting guide according to claim 49, wherein the attachment of the stop is via a linkage.

25

52. A cutting guide comprising:

a portion that is a mirror image of at least one of a joint, an articular surface, a spine, and a structure adjacent to one of a joint, an articular surface, and a spine;

at least one of a guide and a guide aperture for directing movement of a surgical instrument along a predetermined path;

30

a stop for preventing the surgical instrument from deviating from the predetermined

path, wherein one of a position or orientation or shape of the stop is derived using patient specific information.

53. The cutting guide according to claim 52, wherein one of a position or orientation or
5 shape of the stop allows for intra-operative adjustments.

54. A surgical tool comprising:

a template that includes at least one guide for directing movement of a surgical instrument along a predetermined path; and

10 at least one insert attached to the at least one of a guide and a guide aperture, the at least one insert for protecting the template from the surgical instrument.

55. The surgical tool according to claim 54, wherein the template is made of plastic, and wherein the insert is made of metal.

15

56. The surgical tool according to claim 54, wherein the template includes a mold.

57. The surgical tool according to claim 54, wherein the template is a rapid prototype.

20 58. The surgical tool according to claim 54, wherein the insert is removably attached to the template.

59. The surgical tool according to claim 54, wherein the insert snaps onto the template.

25 60. A surgical cutting guide comprising:

a surface that is a mirror image of at least one of a joint, an articular surface, a spine, and a structure adjacent to one of a joint, an articular surface, and a spine;

at least one of a guide and a guide aperture for directing movement of a surgical instrument along a predetermined path, wherein the position or shape or orientation of the at
30 least one of a guide and a guide aperture is based on patient specific information and provides for at least one of a predetermined cut angulation and a predetermined cut height.

61. The surgical tool according to claim 60, further including a stop for inhibiting the surgical instrument from deviating from the predetermined path.

5 62. The surgical tool according to claim 60, wherein the position of the stop is based at least, in part, on patient specific information.

63. A surgical cutting guide comprising:

10 a surface that is a mirror image of at least one of a joint, an articular surface, a spine, and a structure adjacent to one of a joint, an articular surface, and a spine;

at least one of a guide and a guide aperture for directing movement of a surgical instrument along a predetermined path; and

15 a stop that prevents the surgical instrument from deviating from the predetermined path, wherein at least one of the shape, location, and orientation of the stop is based at least, in part, on an image that includes a tissue structure to be preserved, such that the stop prevents the surgical from damaging the tissue structure.

64. A surgical cutting guide for guiding a surgical instrument along a cutting path located on a biological tissue, the cutting guide comprising:

20 a contact surface that conforms to a surface associated with the tissue;

at least one guide for restricting movement of a surgical instrument in a first direction and for allowing the movement of the surgical instrument in a fifth direction along a cutting path into the tissue; and

25 a stop for restricting movement of the surgical instrument in a second direction, wherein the stop is based at least, in part, on patient specific information.

65. A method for guiding a surgical instrument, the method comprising:

30 providing a surgical cutting guide having a contact surface that conforms to a surface associated with a tissue and at least one guide for restricting movement of a surgical instrument in a first direction and for allowing the movement of the surgical instrument in a

fifth direction along the cutting path into the tissue, wherein providing the surgical guide includes:

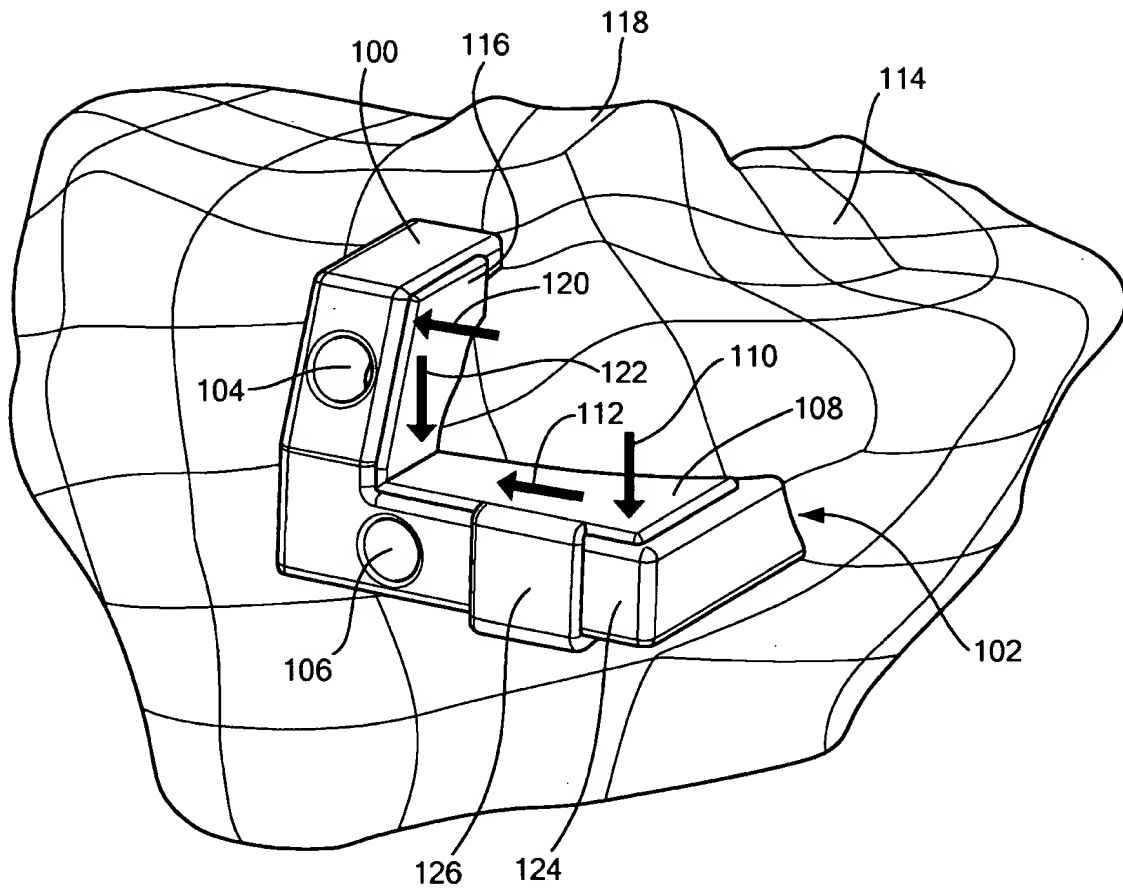
ascertaining patient specific information associated with the tissue; and

incorporating a stop into the guide for restricting movement of the surgical

5 instrument in the second direction, wherein the stop is based at least, in part, on patient specific information.

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**FIG. 1**

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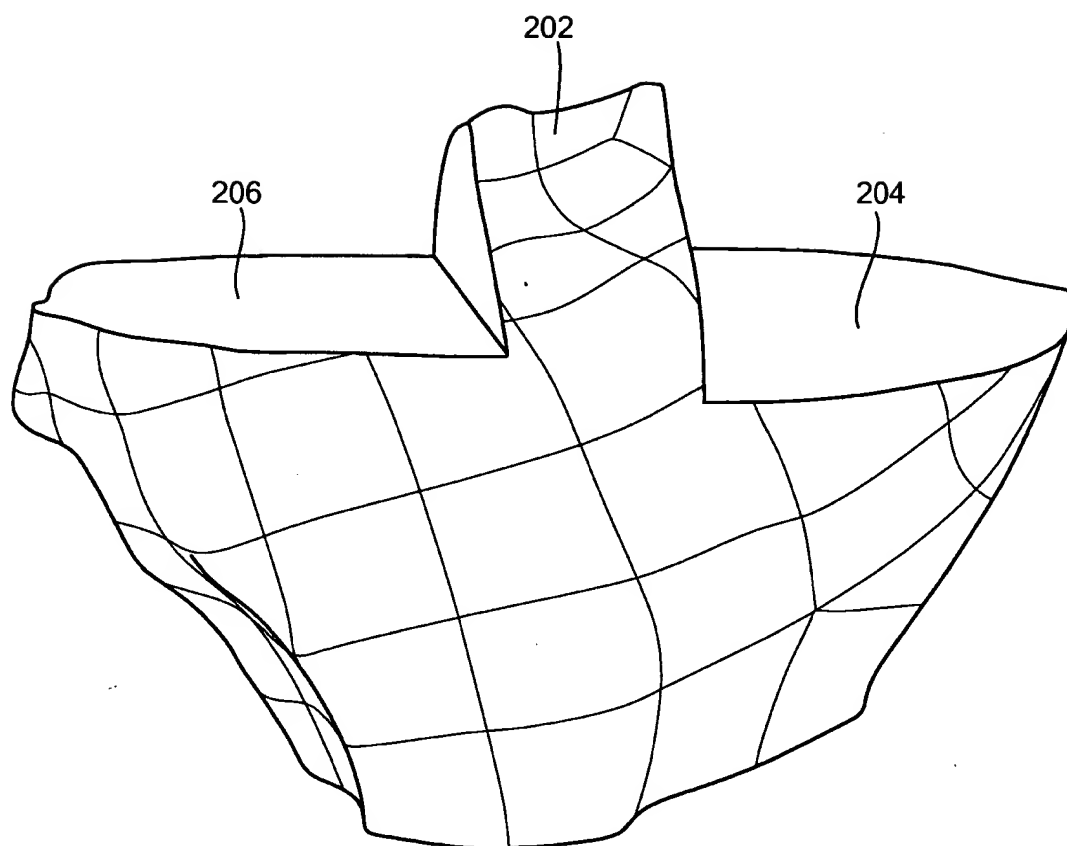


FIG. 2

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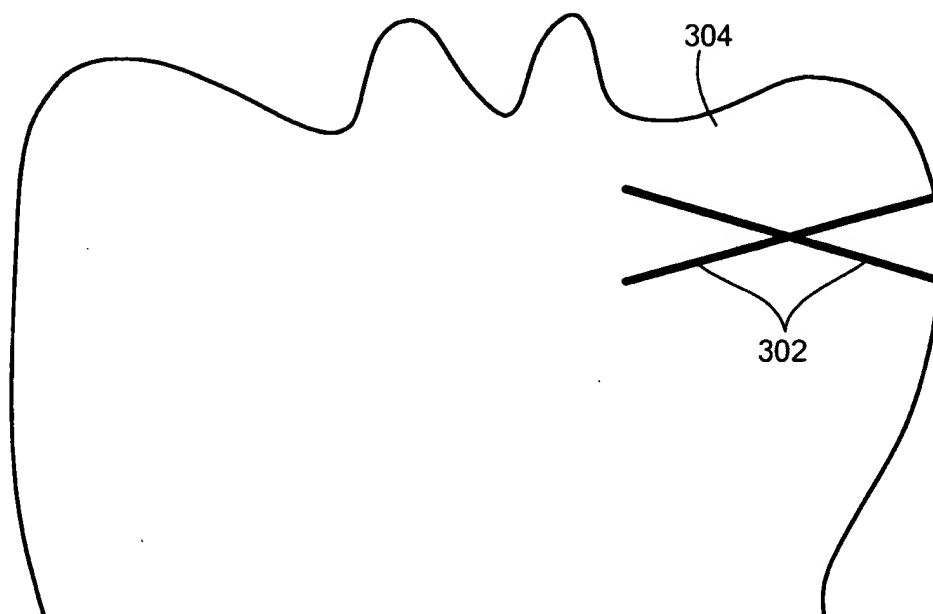


FIG. 3

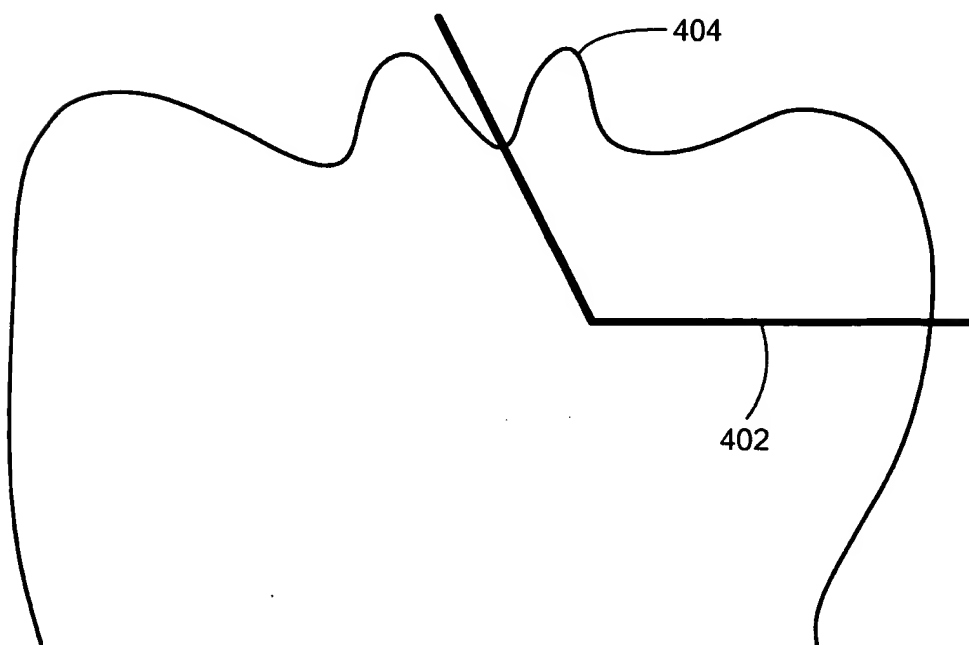
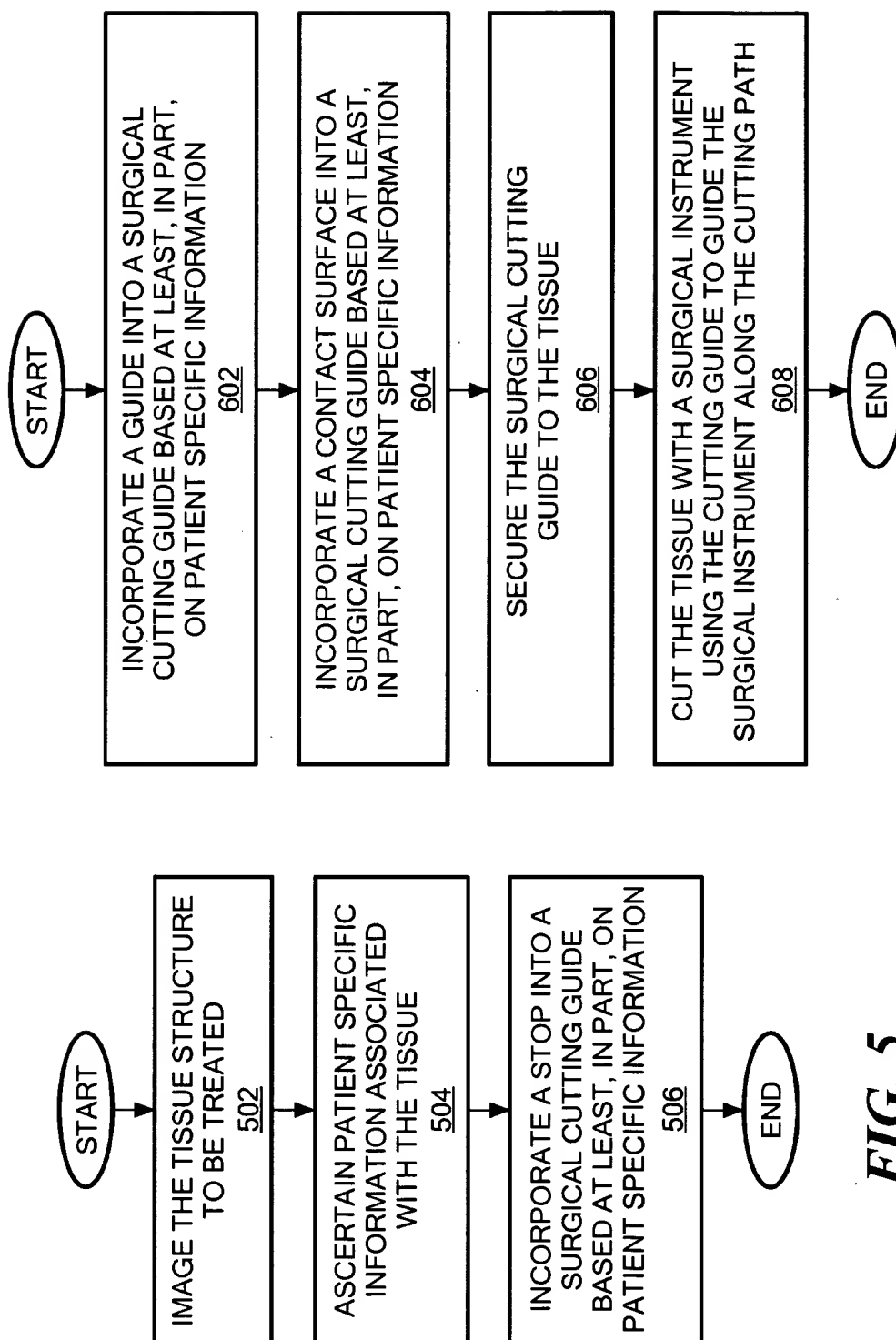


FIG. 4

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[Continued on next page]

(54) Title: SURGICAL CUTTING GUIDE

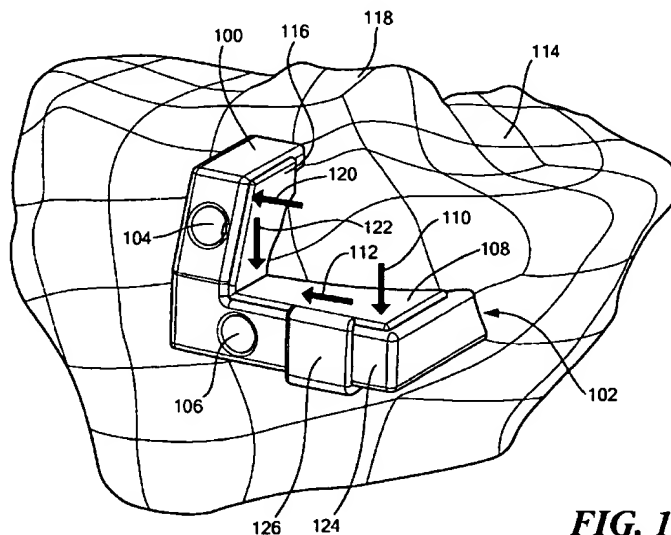


FIG. 1

(57) Abstract: The present invention is directed to a surgical cutting guide for guiding a surgical instrument along a cutting path located on a biological tissue. The surgical guide includes a contact surface that conforms to a surface associated with the tissue and at least one guide for restricting movement of a surgical instrument in a first direction and for allowing the movement of the surgical instrument in a second direction along a cutting path across the surface of the tissue. The guide further contains a stop for restricting movement of the surgical instrument in the second direction along the cutting path. The stop is based at least, in part, on patient specific information.



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Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 337 901 A (BROC CHRISTIAN) 18 October 1989 (1989-10-18)	1-17, 19, 39-53, 60-64
Y	figure 6	18
Y	WO 2004/049981 A (IMAGING THERAPEUTICS INC [US]; BEREZ AARON [US]; FITZ WOLFGANG [US]; L) 17 June 2004 (2004-06-17) paragraphs [0255], [0268], [0269]	18
X	DE 203 03 498 U1 (AESCULAP AG & CO KG [DE]) 3 July 2003 (2003-07-03) figure 1	1
P, X	WO 2007/092841 A (CONFORMIS INC [US]; LANG PHILIPP [US]; FITZ WOLFGANG [US]; BOJARSKI RA) 16 August 2007 (2007-08-16) figure 26W	1-19, 39-53, 60-64
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☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

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- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *G* document member of the same patent family

Date of the actual completion of the international search

24 September 2008

Date of mailing of the international search report

19/02/2009

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INTERNATIONAL SEARCH REPORT

International application No
PCT/US2008/066994

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2005/148843 A1 (ROOSE JEFFREY R [US]) 7 July 2005 (2005-07-07) paragraph [0001] -----	1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2008/066994

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 20-38, 65
because they relate to subject matter not required to be searched by this Authority, namely:
see FURTHER INFORMATION sheet PCT/ISA/210
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers allsearchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search reportcovers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

see additional sheet(s)

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/SA/ 210

Continuation of Box II.1

Claims Nos.: 20-38, 65

The subject-matter of claims 20-38 and 65 relates to a method for treatment of the human body by surgery, since, in view of the description, it is clear that the surgical instrument is guided during a surgical operation (see also claim 22, which further includes the step of cutting the tissue). Therefore, pursuant to Rule 39.1(iv) PCT, the subject-matter of said claims has not been searched.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-19, 39-53, 60-64

a guide having a surface conforming to a patient's tissue for solving the problem of improving the attachment of the guide to said tissue.

2. claims: 54-59

a surgical tool comprising one insert and a template including a guide.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2008/066994

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